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Attorney's Docket No.: 18202-030US1/1111US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Lin Zhi et al.
Serial No. : 10/566,569
Filed : August 21, 2006
Cust. No. : 20985
Title : 6-CYCLOAMINO-2-QUINOLINONE DERIVATIVES AS ANDROGEN
RECEPTOR MODULATOR COMPOUNDS

Art Unit : 1652
Examiner : Unknown
Conf. No. : 6058

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are a Request for Corrected Publication pursuant to 37 C.F.R. § 1.221(b) (4 pages), marked up pages from the publication (3 pages), and a return receipt postcard. It is believed no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

- ☒ The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 18202-030US1/1111US
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Stephanie Seidman



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REQUEST FOR CORRECTED PUBLICATION

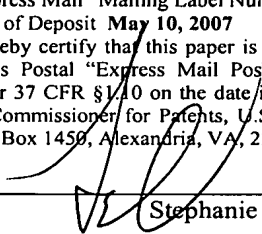
Applicant hereby requests a Corrected Publication pursuant to 37 C.F.R. § 1.221(b). The above-identified application, which published on March 22, 2007 as Publication Number US 2007/0066650 A1, contained the following errors that were created by the USPTO:

On page 32 (Claim 13):

On page 32, Column I, of the published application, in Claim 13, the PTO incorrectly printed compound 187 with a bracket after "Hydroxyethyl" instead of a parenthesis and omitted a hyphen between the "2" and "Hydroxyethyl." Please replace "6-(2(R)-(2 Hydroxyethyl]-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 187);" with -6-(2(R)-(2-Hydroxyethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 187);-. This correction is supported in the application as filed on page on page 71, paragraph [0324].

On page 32, Column I, of the published application, in Claim 13, the PTO incorrectly printed compound 188 by omitting the hyphen between the "2" and "Hydroxyethyl." Please replace "6-(2(R)-(2 Hydroxyethyl)-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 188);" with -6-(2(R)-(2-Hydroxyethyl)-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 188);-. This correction is supported in the application as filed on page 71, paragraph [0324].

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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR § 1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.


Stephanie Seidman

On page 34 (Claim 22):

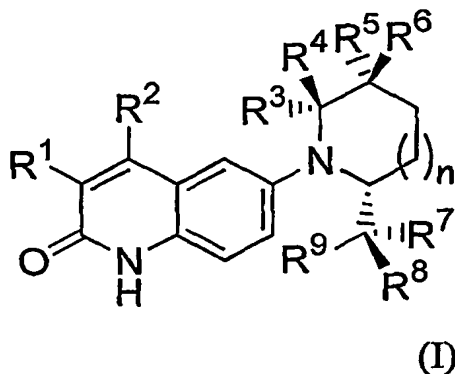
On page 34, Column I of the published application, in claim 22 the PTO incorrectly printed Compound 173 by omitting the "1" from "(1H)" before "-quinolinone" in the compound formula. Please replace "6-(2(R)-(1(R)-Hydroxy-2-acetoxyethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(H)-quinolinone (Compound 173);" with -6-(2(R)-(1(R)-Hydroxy-2-acetoxyethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 173);-. This correction is supported in the application as filed on page 66, paragraph [0297].

On page 34, Column II of the published application, in claim 22 the PTO incorrectly printed Compound 187 by inserting a lowercase "h" instead of an uppercase "H" in "(1H)" before "-quinolinone" in the compound formula. Please replace "6-(2(R)-(2-Hydroxyethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1h)-quinolinone (Compound 187);" with -6-(2(R)-(2-Hydroxyethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 187);-. This correction is supported in the application as filed on page 71, paragraph [0324].

On page 35 (Claim 24):

On page 35, Column I of the published application, in claim 24 the PTO incorrectly printed "NR¹⁰R¹¹" instead of -NR¹⁰R¹¹- as one of the R groups that can be selected for "R9." Please replace claim 24 with the following:

-A pharmaceutical agent comprising a pharmaceutically acceptable carrier and a compound of the formula:



wherein:

R¹ is hydrogen, F, Cl, or C₁-C₃ aliphatic;

R^2 is selected from the group of hydrogen, F, Cl, Br, C_1 - C_4 aliphatic, C_1 - C_4 haloaliphatic, and C_1 - C_4 heteroaliphatic;

R^3 and R^4 each independently is selected from the group of hydrogen, C_1 - C_4 aliphatic, C_1 - C_4 haloaliphatic, C_1 - C_4 heteroaliphatic, optionally substituted aryl and heteroaryl;

R^5 and R^6 each independently is selected from the group of hydrogen, F, Cl, OR^{10} , C_1 - C_4 aliphatic, C_1 - C_4 haloaliphatic, and C_1 - C_4 heteroaliphatic;

R^7 and R^8 each independently is selected from the group of hydrogen, F, Cl, C_1 - C_4 aliphatic, C_1 - C_4 haloaliphatic, and C_1 - C_4 heteroaliphatic; or

R^7 and R^8 taken together form a carbonyl group;

R^9 is selected from the group of halogen, OR^{10} , SR^{10} , $NR^{10}R^{11}$, C_1 - C_4 haloaliphatic, C_1 - C_4 heteroaliphatic, and C_1 - C_4 heterohaloaliphatic;

R^{10} and R^{11} each independently is selected from the group of hydrogen, C_1 - C_4 aliphatic, phenyl, and benzyl; and

$n = 0$ or 1 .—

This correction is supported in the application as originally filed on page 19, paragraph [100].

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Page : 4 of 4

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REMARKS

This Request for Corrected Publication seeks to correct typographical errors in the claims introduced by the Patent and Trademark Office for publication. Marked up copies of the pages to be corrected in the publication accompany this request. Applicant respectfully requests issuance of a corrected publication.

It is believed no fee is due. However, if it is determined that a fee is due, the Office is hereby authorized to charge the fee to Deposit Account No. 06-1050.

Respectfully submitted,

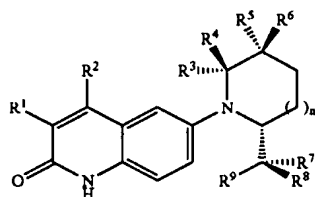
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- 6-(2(R)-(2-Hydroxyethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 187);
- 6-(2(R)-(2-Hydroxyethyl)-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 188);
- 6-(2(R)-Acetyloxyethyl-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 189);
- 6-(2(R)-(1(S)-Hydroxy-2,2,2-trifluoroethyl)-4(S)-fluoro-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 190); and
- 6-(2(R)-(1 (R)-Hydroxy-2,2,2-trifluoroethyl)-4(S)-fluoro-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 191).
14. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a compound of the formula:



wherein:

- R¹ is hydrogen, F, Cl, or C₁-C₃ aliphatic;
- R² is selected from the group of hydrogen, F, Cl, Br, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, and C₁-C₄ heteroaliphatic;
- R³ and R⁴ each independently is selected from the group of hydrogen, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, C₁-C₄ heteroaliphatic, optionally substituted aryl and heteroaryl;
- R⁵ and R⁶ each independently is selected from the group of hydrogen, F, Cl, OR¹⁰, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, and C₁-C₄ heteroaliphatic;
- R⁷ and R⁸ each independently is selected from the group of hydrogen, F, Cl, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, and C₁-C₄ heteroaliphatic; or
- R⁷ and R⁸ taken together form a carbonyl group;
- R⁹ is selected from the group of halogen, OR¹⁰, SR¹⁰, NR¹⁰R¹¹, C₁-C₄ haloaliphatic, C₁-C₄ heteroaliphatic, and C₁-C₄ heterohaloaliphatic;
- R¹⁰ and R¹¹ each independently is selected from the group of hydrogen, C₁-C₄ aliphatic, phenyl, and benzyl; and
- n=0 or 1.
15. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a compound according to claim 2.
16. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a compound according to claim 7.
17. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a compound according to claim 8.

18. A pharmaceutical composition according to claim 14, wherein the compound is an androgen receptor modulator.

19. A pharmaceutical composition according to claim 18, wherein the compound is an androgen receptor antagonist.

20. A pharmaceutical composition according to claim 18, wherein the compound is an androgen receptor agonist.

21. A pharmaceutical composition according to claim 18, wherein the compound is an androgen receptor partial agonist.

22. A pharmaceutical composition according to claim 14, wherein the compound is selected from the group of:

(R)-6-(2-(2,2,2-Trifluoroethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 101);

(R)-6-(2-Phenylthiomethyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 102);

(R)-6-(2-(2,2,2-Trifluoroethyl)-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 103);

(R)-6-(2-Benzylloxymethyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 104);

(R)-6-(2-Diethylaminomethyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 105);

6-(2(R)-Hydroxymethyl-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 106);

6-(2(R)-Fluoromethyl-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 107);

6-(2(R)-Fluoromethyl-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 108);

6-(2(R)-Difluoromethyl-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 109);

6-(2(R)-Fluoromethyl-5 (S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 110);

6-(2(R)-(1 (R)-Hydroxy-2,2,2-trifluoroethyl)-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 111);

6-(2(R)-(1(S)-Hydroxy-2,2,2-trifluoroethyl)-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 112);

6-(2(R)-(1(S)-Hydroxy-2,2,2-trifluoroethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 113);

6-(2(R)-(1 (R)-Hydroxy-2,2,2-trifluoroethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 114);

6-(2(R)-(2,2,2-Trifluoroethyl)-5 (R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 115);

6-(2(R)-(1(S)-Hydroxy-2,2,2-trifluoroethyl)-4(R)-hydroxy-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 116);

6-(2(R)-(1 (R)-Hydroxy-2,2,2-trifluoroethyl)-4(R)-hydroxy-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 117);

6-(2(R)-(1(S)-Fluoro-2,2,2-trifluoroethyl)-4(S)-fluoro-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 118);

6-(2(R)-(1 (R)-Hydroxyethyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 160);

6-(2(R)-Trifluoroacetyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 161);

6-(2(R)-(1(S)-Hydroxypentyl-1-piperidinyl)-4-trifluoromethyl-2 (1H)-quinolinone (Compound 162);

6-(2(R)-(1 (R)-Hydroxypentyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 163);

6-(2(R)-(1 (R)-Hydroxyethyl)-5 (R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 164);

6-(2(R)-(1-Hydroxy-1-methylethyl)-5 (R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 165);

6-(2(R)-(1(S)-Hydroxy-1-cyclopropylmethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 166);

6-(2(R)-(1 (R)-Hydroxy-1-cyclopropylmethyl)-5 (R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 167);

6-(2(R)-(1(S)-Hydroxypropyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 168);

6-(2(R)-(1 (R)-Hydroxypropyl)-5 (S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 169);

6-(2(R)-(1 (R)-Hydroxypropyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 170);

6-(2(R)-(1(S)-Hydroxypropyl)-5 (S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 171);

6-(2(R)-(1 (R)-Hydroxy-2-methylpropyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 172);

→ 6-(2(R)-(1 (R)-Hydroxy-2-acetoxyethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 173);

6-(2(R)-(1 (R)-Hydroxy-2-chloroethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 174);

6-(2(R)-(2-Hydroxyethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 175);

6-(2(R)-(2-Oxoethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 176);

6-(2(R)-Acetyloxymethyl-6(R)-methyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 177);

6-(2(R)-(1 (R)-Chloro-2-hydroxyethyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 178);

6-(2(R)-Hydroxymethyl-6(R)-methyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 179);

6-(2(R)-(1 (R)-Hydroxy-2,2,2-trifluoroethyl)-6(R)-methyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 180);

6-(2(R)-(1(S)-Hydroxy-2,2,2-trifluoroethyl)-5(R)-methyl-1-pyrrolidinyl)-4-chlorodifluoromethyl-2(1H)-quinolinone (Compound 181);

6-(2(R)-(1 (R)-Hydroxy-2,2,2-trifluoroethyl)-5(R)-methyl-1-pyrrolidinyl)-4-chlorodifluoromethyl-2(1H)-quinolinone (Compound 182);

6-(2(R)-(1(S)-Hydroxy-2,2,2-trifluoroethyl)-5(S)-methyl-1-pyrrolidinyl)-4-chlorodifluoromethyl-2(1H)-quinolinone (Compound 183);

6-(2(R)-(2(S)-Hydroxy-3,3,3-trifluoropropyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 184);

6-(2(R)-(2(R)-hydroxy-3,3,3-trifluoropropyl)-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 185);

6-(2(R)-Acetyloxymethyl-6(R)-methyl-1-piperidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 186);

6-(2(R)-(2-Hydroxyethyl)-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 187); ←

6-(2(R)-(2-Hydroxyethyl)-5(S)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 188);

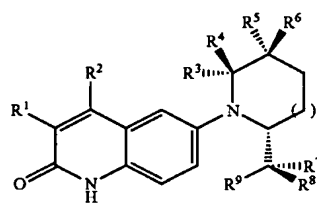
6-(2(R)-Acetyloxyethyl-5(R)-methyl-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 189);

6-(2(R)-(1(S)-Hydroxy-2,2,2-trifluoroethyl)-4(S)-fluoro-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 190); and

6-(2(R)-(1 (R)-Hydroxy-2,2,2-trifluoroethyl)-4(S)-fluoro-1-pyrrolidinyl)-4-trifluoromethyl-2(1H)-quinolinone (Compound 191).

23. A pharmaceutical composition according to claim 14, wherein the composition is formulated for oral, topical, intravenous, suppository or parenteral administration.

24. A pharmaceutical agent comprising a pharmaceutically acceptable carrier and a compound of the formula:



(I)

wherein:

R¹ is hydrogen, F, Cl, or C₁-C₃ aliphatic;

R² is selected from the group of hydrogen, F, Cl, Br, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, and C₁-C₄ heteroaliphatic;

R³ and R⁴ each independently is selected from the group of hydrogen, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, C₁-C₄ heteroaliphatic, optionally substituted aryl and heteroaryl;

R⁵ and R⁶ each independently is selected from the group of hydrogen, F, Cl, OR¹⁰, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, and C₁-C₄ heteroaliphatic;

R⁷ and R⁸ each independently is selected from the group of hydrogen, F, Cl, C₁-C₄ aliphatic, C₁-C₄ haloaliphatic, and C₁-C₄ heteroaliphatic; or

R⁷ and R⁸ taken together form a carbonyl group;

R⁹ is selected from the group of halogen, OR¹⁰, SR¹⁰, NR¹⁰R, C₁-C₄ haloaliphatic,

C₁-C₄ heteroaliphatic, and C₁-C₄ heterohaloaliphatic;

R¹⁰ and R¹¹ each independently is selected from the group of hydrogen, C₁-C₄ aliphatic, phenyl, and benzyl; and n=0 or 1.

25. A method of modulating androgen receptor activity in a mammal, comprising administering to said mammal a pharmaceutically effective amount of a compound according to claim 1.

26. A method for modulating a process in a mammal mediated by androgen receptor, comprising administering to said mammal a pharmaceutically effective amount of a compound according to claim 1.

27. A method according to claim 25, wherein said mammal has a condition mediated by an androgen receptor.

28. A method according to claim 27, wherein said condition is selected from the group of acne, male-pattern baldness, impotence, sexual dysfunction, wasting diseases, frailty, hirsutism, hypogonadism, prostatic hyperplasia, osteoporosis, cancer cachexia and hormone-dependent cancers.

29. A method according to claim 27, wherein said condition is susceptible to treatment with a therapy selected from the group of male hormone replacement therapy, female androgen replacement therapy and stimulation of hematopoiesis.

30. A compound according to claim 2, wherein the compound is an androgen receptor antagonist.

31. A compound according claim 2, wherein the compound is an androgen receptor agonist.

32. A compound according claim 2, wherein the compound is an androgen receptor partial agonist.

33. A pharmaceutical composition according to claim 15, wherein the compound is an androgen receptor modulator.

34. A pharmaceutical composition according to claim 33, wherein the compound is an androgen receptor antagonist.

35. A pharmaceutical composition according to claim 33, wherein the compound is an androgen receptor agonist.

36. A pharmaceutical composition according to claim 33, wherein the compound is an androgen receptor partial agonist.

37. A pharmaceutical composition according to claim 16, wherein the compound is an androgen receptor modulator.

38. A pharmaceutical composition according to claim 37, wherein the compound is an androgen receptor antagonist.

39. A pharmaceutical composition according to claim 37, wherein the compound is an androgen receptor agonist.

40. A pharmaceutical composition according to claim 37, wherein the compound is an androgen receptor partial agonist.

41. A pharmaceutical composition according to claim 17, wherein the compound is an androgen receptor modulator.

42. A pharmaceutical composition according to claim 41, wherein the compound is an androgen receptor antagonist.

43. A pharmaceutical composition according to claim 41, wherein the compound is an androgen receptor agonist.

44. A pharmaceutical composition according to claim 41, wherein the compound is an androgen receptor partial agonist.

* * * * *